Mountain-Pacific Quality Health . . . The go-to resource for driving innovation in health care systems

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Montana Medicaid Prior Authorization Request Form for Use of Olysio®(simeprevir)

Olysio® Initial Approval Form

Note: Forms completed by the providing pharmacy will not be accepted. Forms must be completed by the prescribing office.

Patient's Name:	Patient's Medicaid ID#:
Patient's DOB:	Patient's Gender:
Provider's Name:	Provider's Specialty:
Provider's Phone #:	Provider's Fax #:
Today's Date:	Anticipated Olysio® Start Date:

I. Patient Readiness Evaluation:

Patient psychosocial readiness is a critical component for Hepatitis C treatment success. It is important that any potential impediments to the effectiveness of treatment have been identified and that a plan for dealing with these impediments has been developed. The patient must be educated that abuse of alcohol may cause further liver damage and that abuse of IV injectable drugs will increase the risk of re-infection of Hepatitis C if the virus is cleared. Given the high cost of Hepatitis C treatment, we want to ensure that both the provider and the patient feel that the patient is committed to effectively start and successfully adhere to treatment. We highly recommend that you use a patient readiness evaluation tool such as Prep-C, a free interactive online tool which can be found at the following website: https://prepc.org/. **Please discuss the following questions with your patient, document their responses below, and have patient sign page 2:**

1. **Does patient have a history of alcohol abuse? Yes No**
   - If yes, how long has it been since patient last used alcohol?
   - If yes, is patient attending a support group or receiving counseling? Yes No
2. **Does patient have a history of injectable drug abuse? Yes No**
   - If yes, how long has it been since patient last used an injectable drug?
   - If yes, is patient attending a support group or receiving counseling? Yes No
3. **Does patient have a history of any other controlled-substance abuse? Yes No**
   - If yes, how long has it been since patient last used this substance?
   - If yes, is patient attending a support group or receiving counseling? Yes No
4. **Does patient have difficulties with medication compliance and/or showing up for appointments? Yes No**
   - If yes, how will compliance/ involvement be improved?
5. **Does patient have mental health conditions that are not being adequately treated? Yes No**
   - If yes, please explain, and state the plan for treatment:
6. **Does patient have adequate social support? Yes No**
   - If not, please state a plan to improve support:

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MT Medicaid Hepatitis C Patient Readiness Criteria:

1. Patient must not have a history of alcohol abuse, injectable drug abuse, and/or other controlled-substance abuse for at least 6 months prior to starting Hepatitis C treatment. Patient involvement in a support group or counseling is highly encouraged for successful abstinence.

2. Patient must be reasonably compliant with all current medications that are being prescribed for all disease states/conditions to be considered eligible for Hepatitis C treatment.

3. Patient must have a history of showing up for scheduled appointments/labs leading up to the prescribing of Hepatitis C treatment.

4. If patient has mental health conditions, patient must be compliant with mental health medications and/or psychotherapy. If patient has mental health conditions that are not currently being treated, then a mental health consult to assess for patient readiness will be required before Hepatitis C treatment can begin.

Patient signature:_____ **Date:**_____

II. MT Medicaid Olysio® Requirements:

A. HCV genotype [and subtype (1a or 1b) if Genotype 1] – attach results. Note if Genotype 1a, then must provide lab result of screening of NS3 Q80K polymorphism. If polymorphism is present, alternative therapy should be considered due to decreased Olysio® efficacy.

_____

B. Documentation of extent of liver damage must be included [liver biopsy fibrosis stage (F0-F4), or any of the following non-invasive test results: APRI score, FibroSure score, or FibroScan results]

_____

C. Please provide Child-Pugh Classification Score and Grade by evaluating each of 5 measures in table below:
Total points: _____ Child Pugh Grade: _____

	Points Assigned		
PARAMETER	**1**	**2**	**3**
Ascites	Absent	Slight	Moderate
Bilirubin, total (mg/dL)	1.0-2.0	2.0-3.0	>3.0
Albumin (g/dL)	>3.5	2.8-3.5	<2.8
Prothrombin Time			
-Seconds prolonged	1.0-4.0	4.0-6.0	>6.0
-International normalized ratio (INR)	<1.7	1.7-2.3	>2.3
Encephalopathy*	None	Grade 1-2	Grade 3-4

*Encephalopathy is classified as Grade 0 to 4:

Grade
0-no abnormality detected
1-shortened attention span, impaired addition and subtraction skills, mild euphoria or anxiety
2-Lethargy, apathy, disoriented to time, personality change, inappropriate behavior
3-Somnolence, semi-stupor, responsive to stimuli, confused when awake, gross disorientation
4-Coma, little or no response to stimuli, mental state not testable

Child Pugh Grade	Description	Total Points
A	Mild; well-compensated disease	**5-6**
B	Moderate; significant functional compromise	**7-9**
C	Severe; decompensated disease	**10-15**

Adapted from: Pugh RN, Murray-Lyon IM, Dawson JL, Pietroni MC, Williams R. Transection of the oesophagus for bleeding oesophageal varices. Br J Surg. 1973 Aug;60(8):646-9. PMID.

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D. List any previously tried Hepatitis C treatments, dates treated, and response:

_____

E. **Patient must meet <u>ALL</u> of the following criteria:** (Please check all that apply)
***Any requests not meeting criteria will require review by the MT Medicaid DUR Board.**

- ○ All chart notes related to Hepatitis C evaluation/treatment must be included
- ○ Patient Readiness Evaluation (page 1) must be completed and patient must meet all of the Patient Readiness Criteria listed on page 2
- ○ Documentation of extent of liver damage must be included (see page 2)
  - ○ Individual is considered at highest risk for Hepatitis-C related complications (must have liver fibrosis staging of F3 or F4, be a liver transplant recipient, or have severe extrahepatic manifestations)
- ○ Must not have moderate or severe hepatic impairment (Child-Pugh Class B or C)
- ○ Must not have decompensated cirrhosis
- ○ Diagnosis of chronic hepatitis C infection with HCV genotype 1 or 4
- ○ Does patient have genotype 1a? Yes/ No **(please circle**). **If yes, must provide lab result of screening of NS3 Q80K polymorphism.** If polymorphism is present, alternative therapy should be considered due to decreased efficacy.
- ○ Must not be of East Asian ancestry
- ○ Never had previous treatment with Olysio® or other HCV NS3/4A protease inhibitors [ex: Victrelis® (boceprevir) or Incivek® (telaprevir)]
- ○ Patient is 18 years of age or older
- ○ Must be prescribed by a gastroenterologist, infectious disease specialist, or a hepatologist who provides initial consultation and continues to monitor patient throughout course of treatment
- ○ If taking with ribavirin, female patient or male patient's female partner must not be pregnant or planning to become pregnant during treatment or within 6 months after stopping treatment.
- ○ Olysio® must be taken along with required concomitant meds (ex: ribavirin + peginterferon alfa or Sovaldi®) depending on HCV genotype
- ○ Patient does not have severe renal impairment (CrCl <30ml/min) or end stage renal disease requiring dialysis
- ○ Patient must not have had treatment with any other Hepatitis C medications within the last 6 months
- ○ Patient must not be taking any of the following medications (please circle if patient is taking): amiodarone (if taken with Sovaldi®), erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, voriconazole, fluconazole, rifampin, rifabutin, rifapentine, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, dexamethasone, cisapride, cobicistat-containing product, efavirenz, delavirdine, etravirine, nevirapine, darunavir/ritonavir, atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, cyclosporine, milk thistle, or St. John's wort.

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F. **Requested Treatment Regimen:** (Check the regimen that applies)

- ○ **HCV Genotype 1 or 4 Treatment-Naïve/Prior Relapser with or without cirrhosis, who is not co-infected with HIV:** Olysio + IFN + RBV x 12 weeks, followed by an additional 12 weeks of IFN + RBV
- ○ **HCV Genotype 1 or 4 Treatment-Naïve/Prior Relapser without cirrhosis, who is co-infected with HIV:** Olysio + IFN + RBV x 12 weeks, followed by an additional 12 weeks of IFN + RBV
- ○ **HCV Genotype 1 or 4 Treatment-Naïve/Prior Relapser with cirrhosis, who is co-infected with HIV:** Olysio + IFN + RBV x 12 weeks, followed by an additional 36 weeks of IFN + RBV
- ○ **HCV Genotype 1 or 4 Prior Non-Responder (including partial and null responders) with or without cirrhosis, with or without HIV coinfection:** Olysio + IFN + RBV x 12 weeks, followed by an additional 36 weeks of IFN + RBV
- ○ **HCV Genotype 1 (no HIV co-infection) treatment-naïve or treatment experienced without cirrhosis:** Olysio + Sovaldi x 12 weeks
- ○ **HCV Genotype 1 (no HIV co-infection) treatment-naïve or treatment experienced with cirrhosis:** Olysio + Sovaldi x 24 weeks

***Preferred treatment may be subject to the MT Medicaid Preferred Drug List.**

Limitations:

1. Olysio® Quantity Limit and Sovaldi® Quantity Limit of **28 capsules per 28 days** (one Olysio® capsule = 150 mg simeprevir and one Sovaldi® tablet = 400 mg sofosbuvir).
2. **Initial approval** will be granted for **4 weeks**.
3. Continuation of therapy beyond 4 weeks will require completion of **Olysio® Renewal Form**.
4. If taking Olysio with IFN + RBV, HCV RNA viral load will need to be drawn at weeks 4, 8, and 12.

Provider's Signature:_____Date:_____

Please complete form, attach documentation, and fax to:
Medicaid Drug Prior Authorization Unit at 1-800-294-1350

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Montana Medicaid Prior Authorization Request Form for Use of Olysio® (simeprevir)

Olysio® Renewal Form

Note: Forms completed by the providing pharmacy will not be accepted. Forms must be completed by the prescribing office.

Patient's Name:	Patient's Medicaid ID#:
Patient's DOB:	Patient's Gender:
Provider's Name:	Provider's Specialty:
Provider's Phone #:	Provider's Fax #:
Date:	

Date Olysio® was started:_____

Treatment Regimen: (check one)

- ○ **HCV Genotype 1 or 4 Treatment-Naïve/Prior Relapser with or without cirrhosis, who is not co-infected with HIV:** Olysio + IFN + RBV x 12 weeks, followed by an additional 12 weeks of IFN + RBV
- ○ **HCV Genotype 1 or 4 Treatment-Naïve/Prior Relapser without cirrhosis, who is co-infected with HIV:** Olysio + IFN + RBV x 12 weeks, followed by an additional 12 weeks of IFN + RBV
- ○ **HCV Genotype 1 or 4 Treatment-Naïve/Prior Relapser with cirrhosis, who is co-infected with HIV:** Olysio + IFN + RBV x 12 weeks, followed by an additional 36 weeks of IFN + RBV
- ○ **HCV Genotype 1 or 4 Prior Non-Responder (including partial and null responders) with or without cirrhosis, with or without HIV coinfection:** Olysio + IFN + RBV x 12 weeks, followed by an additional 36 weeks of IFN + RBV
- ○ **HCV Genotype 1 (no HIV co-infection) treatment-naïve or treatment experienced without cirrhosis:** Olysio + Sovaldi x 12 weeks
- ○ **HCV Genotype 1 (no HIV co-infection) treatment-naïve or treatment experienced with cirrhosis:** Olysio + Sovaldi x 24 weeks

Renewal Requirements: The following requirements must be met. (Check all that apply)

- ○ Concomitant medications (IFN + RBV or Sovaldi®) must not have been discontinued.
- ○ Patient must have been compliant with therapy as per protocol
- ○ If taking Olysio® with IFN + RBV, week 4, 8, and 12 HCV RNA levels must be documented below:

Week 4 HCV RNA viral load (IU/ml): _____ Lab Date: _____
Week 8 HCV RNA viral load (IU/ml): _____ Lab Date: _____
Week 12 HCV RNA viral load (IU/ml): _____ Lab Date: _____

Renewal Continued…Page 1 of 2

Renewal Limitations:

1. If taking Olysio® with IFN + RBV and **week 4, 12, or 24** HCV RNA is ≥ **25 IU/ml**, further authorization will be **denied**.
2. If taking Olysio® with IFN + RBV and **week 4, 12, or 24** HCV RNA is **< 25 IU/ml**, therapy will be **authorized for 4 weeks** (for a maximum total of 12 weeks of Olysio® therapy). Dosing will be limited to 1 capsule per day (28 capsules per 28 days).
3. If taking with Sovaldi® and patient meets criteria, Olysio and Sovaldi will each be approved in 4 week increments (28 capsules per 28 days) until total approved time is reached (12 weeks or 24 weeks total).

Note: Olysio® Renewal Form will need to be submitted for each 4 week authorization.

Provider's Signature:_____**Date:**_____

Please complete form, attach documentation, and fax to:
Medicaid Drug Prior Authorization Unit at 1-800-294-1350